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10/587,542	07/28/2006	Ooi Kiang Tan	P71388US0	9656

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EXAMINER	
LUM, LEON YUN BON	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,542	TAN ET AL.	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 8-13, 15-19, 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Ewart *et al.* (US 5,922,537) ("Ewart").

i. Independent claims 1 and 15 are anticipated

Ewart teaches a device comprising three layers: a metallization layer overlaid with a ferroelectric material, which is overlaid with a silica layer. Column 14, lines 54-63 (describing the three layers as a metallization layer, a passive dielectric layer and an outer dielectric layer) and column 16, lines 62-65 (describing the passive dielectric layer as a ferroelectric material). Together, the ferroelectric material and silica layer teach "a ferroelectric transducer," as claimed. Moreover, the metal layer can comprise two electrodes, thereby teaching the "first and second electrodes," as claimed. Column 17, line 1 and Figure 8 (illustrating numbers 80 and 82 as being directed to the two electrodes). Ewart also teaches a competition assay, in which an analyte immobilized on the silica layer competes with free analyte for binding to a recognition molecule provided in solution; hence since there is analyte in solution, Ewart teaches "a biological

sample disposed adjacent said transducer," as claimed. Column 9, lines 7-8; column 17, lines 3-4; and Figure 8. Ewart further teaches a sensing element attached to the device, thereby teaching "an electric signal detector," as claimed. Column 18, lines 39-54 and Figures 10 and 11.

Ewart also teaches a method of using the aforementioned device, by describing the step of introducing a sample onto the device and detecting an electrical change in the device established through the two electrodes, which in turn necessarily polarizes analyte in the sample described. Column 17, lines 7-18. Indeed, Figure 8 illustrates an electric field between the two electrodes. Moreover, Ewart teaches in one embodiment that the device can be a capacitance sensor and that a change in capacitance is detected. *Id.* Hence, as would be recognized by one skilled in the art, the presence of two capacitor plates next to each other with the application of voltage would necessary produce an electric field. Consequently, since a change in capacitance is detected, an electric field is necessarily and inherently established. Consequently, Ewart teaches the "establishing" step as claimed.

ii. Dependent claims 4, 8-9, 12-13, 16-18, 21 and 23-24 are anticipated

Regarding claim 4, the claims are directed to an embodiment where, generally, the transducer and sample are in between the two electrodes. The specification does not reasonably limit these elements to a particular arrangement. With this in mind, Applicants are directed to Figure 8 of Ewart, which illustrates one embodiment of the device comprising a portion of the ferroelectric material and sample in between the two electrodes. Figure 8 (illustrating number 90 as the ferroelectric material and numbers

80 and 82 as the two electrodes). Moreover, as described above, Ewart inherently teaches the step of establishing an electric field.

Regarding claims 8 and 17, Ewart teaches that the ferroelectric material can be a ferroelectric polymer. Column 15, lines 50-51.

Regarding claims 9 and 18, the ferroelectric layer is a thin film as illustrated in Figure 8 and corresponding citations in the specification.

Regarding claims 10 and 19, Ewart teaches that the analyte can be a protein. Table 1.

Regarding claims 11 and 22-23, Ewart teaches that, in lieu of a competition immunoassay, a direct immunoassay can be performed with phage particles, i.e., the recognition molecules described above. Column 3, lines 14-18. Since a direct immunoassay involves only the phage particle and analyte, the analyte will necessarily be immobilized directly onto the transducer, as claimed.

Regarding claims 13 and 24, Ewart teaches that, instead of performing a competition assay, a sandwich assay can be performed. Column 3, lines 14-18. Therefore, since the analyte is the object to be detected, the sandwich assay format necessarily requires a probe molecule, as claimed.

Regarding claim 12, Ewart teaches that the silica layer is optional; hence, the analyte can be bound directly to the ferroelectric layer, as claimed. Column 14, lines 61-63 and column 15, lines 13-14.

Regarding claim 16, since the electrodes have stored charge for performing capacitive detection, a voltage source is necessarily provided.

Regarding claim 21, since the silica layer on the ferroelectric layer is in contact with the sample solution, Ewart teaches the claimed embodiment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewart, cited above.

In addition to the aforementioned device, Ewart teaches one embodiment comprising a dual-sided device with the same layers on each side. Column 16, lines 20-37. The purpose of having a dual-sided device is to be able to conduct a reference test. Column 16, lines 38-39.

Ewart does not teach the step of determining a "difference" between a sample response and a reference response, as claimed. However, it would have been obvious to one of ordinary skill in the art to modify Ewart's teaching to include a step of comparing the sample and reference signals. Indeed, there is but one purpose for performing reference test as described above – i.e., to determine a more accurate

sample reading, which can only be accomplished by determining a difference between the sample and reference signals.

Regarding claim 3, Ewart evidences analyte detection through changes in electrical signal, as described above. Implicit in this description is the correlation between signal level and analyte concentration. Hence, Ewart inherently teaches that the signal is indicative of analyte concentration, as claimed.

Claims 1, 4-7 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stasiak *et al.* (US 7,163,659) ("Stasiak") in view of Alexander (US 4,514,441), and in light of Ewart, cited above.

i. Claims 1, 4-5 and 20 are obvious

Stasiak teaches a capacitive sensor comprising two electrodes, one with a functional layer thereon and the other in contact with a sample such that the sample is between the two electrodes. Column 6, lines 52-65; column 12, lines 1-22; and Figure 7. Stasiak, therefore, teaches the "placing" step and a "first electrode" and "second electrode," as claimed. Stasiak also teaches a method of using the aforementioned device by introducing a sample onto the device and placing a current or voltage through at least one of the electrodes, which necessarily polarizes the analyte; hence, Stasiak teaches the "sensing" step, as claimed. Column 6, line 52 to column 7, line 18; and column 12, lines 40-43. Moreover, as would be recognized by one skilled in the art, the presence of two capacitor plates next to each other with the application of voltage would necessary produce an electric field. Consequently, since a change in capacitance is

detected, an electric field is necessarily and inherently established. Stasiak, therefore, teaches the "establishing" step. Furthermore, by describing a layer of nanowires that act in concert with the electrodes to produce a detection signal, Stasiak teaches the claimed "transducer." Column 6, line 52 to column 7, line 18. Notably, the nanowires are coated with a dielectric material. Column 3, lines 27-29 and column 4, lines 9-12.

Stasiak, however, does not teach a ferroelectric material on the transducer.

Alexander teaches that barium titanate is commonly employed as a dielectric material for a variety of electrical applications, including a substrate for sensing films. Column 1, lines 9-20. Barium titanate is well-known to one of ordinary skill in the art as a ferroelectric material, as evidenced by Ewart. Column 16, lines 63-64.

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Stasiak's method by using barium titanate as the dielectric layer, as taught by Alexander. Indeed, given Alexander's description that barium titinate is a well known dielectric, the skilled artisan would have a reason for using barium titinate in Stasiak's device. Moreover, Stasiak generally teaches that any dielectric material can be used and does not preclude a specific material. Accordingly, the skilled artisan would have a reasonable expectation of success in applying Alexander's barium titanate to Stasiak's method.

ii. Dependent claims 6 and 7 are obvious

Regarding claims 6 and 7, the claims are obvious for the foregoing reasons and also for the following rationale. Stasiak teaches the step of applying an electrical current to at least one of the electrodes. Column 6, lines 65-66. As would have been

apparent to one of ordinary skill in the art, capacitive sensing necessarily involves either applying a current and measuring a change in voltage or applying a voltage and measuring a change in current. Hence, it would have been obvious to perform either method using the sensor of Stasiak.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ewart, cited above, in view of Pankratz (US 4,810,639).

Ewart is described above, but does not teach the step of "removing a remaining portion of said sample," as claimed.

Pankratz teaches a washing step to remove sample constituents and contaminants not bound to the solid phase. Column 8, lines 41-45.

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Ewart's method by including a washing step to remove unbound analytes, as taught by Pankratz. The skilled artisan would have been motivated to perform the modification based on Pankratz's teaching that the washing step removes contaminants. Indeed, this step would prevent any interference by the contaminants in affecting the assay result. Moreover, Pankratz's washing step is provided in the form of an immunoassay, which is within the scope of Ewart's assay. Accordingly, the skilled artisan would have had a reasonable expectation of success in combining Pankratz's step with Ewart's method.

Response to Arguments

Applicants arguments in the Response filed February 13, 2009 have been fully considered. For the following reasons, they do not overcome the previously applied art rejections.

I. Rejection of claims 1, 4, 8-13, 15-19 and 21-24 under Ewart

Applicants traverse the rejection of claims 1, 4, 8-13, 15-19 and 21-24 under 35 U.S.C. § 102(b) as being anticipated by Ewart. *Response*, pages 9-10. Specifically, Applicants argue that Ewart "teaches away" from the claimed invention as amended because it describes a silica layer and does not allow "placing a sample on a surface of a ferroelectric transducer," as the present invention allegedly claims. *Id* at 9. Applicants, moreover, assert that Ewart's three-layer device "cannot be equated with the present invention" because the ferroelectric layers of Ewart supposedly operate different from the claimed transducer. *Id*. at 9-10.

Applicants' arguments imply that the ferroelectric transducer, as claimed, does not comprise a coating – i.e., the analyte directly contacts a ferroelectric layer. The claim language and specification, however, do not support this notion. The claim currently recites a "on a surface ferroelectric transducer" (emphasis added) and does not limit the transducer to simply a ferroelectric layer. Moreover, the specification indicates that the ferroelectric transducer can be a multilayer embodiment that comprises a coating on its surface. *Specification*, page 4 (referring to a top surface of the ferroelectric transducer as "may or ***may not*** be formed with a ferroelectric material" and can have a "coating material") (emphasis added). Furthermore, dependent claim 12 recites an analyte that "is immobilized directly on a ferroelectric layer of said

transducer." By the doctrine of claim differentiation, base claim 1 has a broader scope that necessarily includes a layer on top of the ferroelectric layer. Accordingly, absent claim language that removes any coating material on the ferroelectric material, the transducer, as claimed, can include such a coating. Consequently, Ewart's ferroelectric transducer, which can include a silica layer, appropriately teaches the claimed ferroelectric transducer.

Moreover, Ewart indicates that the outer silica layer is not an integral part of the transducer and can be removed. Column 15, lines 12-13 (indicating that by removing the outer dielectric layer, sensitivity can be increased). Accordingly, because the outer silica layer is removed, the analyte will be in direct contact with the ferroelectric passivation layer that is on top of the metallization layer. Therefore, even if the claims are in line with claim 12 and are directed to an analyte directly contacting the ferroelectric layer, Ewart describes this very embodiment.

II. Rejection of claims 2 and 3 over Ewart

Applicants traverse the rejection of claims 2 and 3 under 35 U.S.C. § 103(a) as being obvious over Ewart. *Response*, page 10. Specifically, Applicants allege that the amendment to claims 1 and 15 negate Ewart as a reference. For the foregoing reasons, however, Ewart appropriately teaches the claimed invention.

III. Rejection of claims 1, 4-7 and 20 over Stasiak in view of Alexander, and in light of Ewart

Applicants traverse the rejection of claims 1, 4-7 and 20 under 35 U.S.C. § 103(a) as being obvious over Stasiak in view of Alexander. *Response*, pages 10-12.

Specifically, Applicants argue that Stasiak does not teach an electrode for establishing an electric field to polarize an analyte. *Id.* at 12. Moreover, Applicants assert that Stasiak allegedly does not teach the "specific configuration of the transducer, samples and electrodes" currently claimed. *Id.*

Applicants' argument appears to rest on Stasiak's description that the electrodes act as capacitors, thereby allegedly only acting to provide electrical communication between the nanowires and does not establish an electric field. *Response*, page 12. In contrast, by applying an electric current to the electrodes (*Stasiak*, column 6, lines 65-66), although they function as capacitive plates, an electric field will necessarily be produced due to the presence of charge. The presence of an electric field would be able to polarize analyte present on the nanowires, absent evidence to the contrary. Applicants have not provided a reason why the electric field produced through the capacitive plates would not produce polarization, as claimed.

Applicants also opine that the "configuration" of claimed transducer, samples and electrodes are different from that provided by Stasiak. Contrary to this argument, Stasiak teaches the claimed configuration. Applicants specifically cite to claims 4, 5 and 20, directed to a transducer and sample between two electrodes. *Response*, page 12. Stasiak, as cited above, however, teaches this configuration in Figure 7 and the accompanying description in the disclosure. Column 12, lines 1-22 (referring to nanowires 16, plate 42 and conductive film 14). Here, analyte in the sample attaches to the nanowire, acting as a transducer. Both of these elements are in between two electrodes. Accordingly, Stasiak fully teaches the claimed configuration.

III. Rejection of claim 14 over Ewart in view of Pankratz

Applicants traverse the rejection of claim 14 under 35 U.S.C. § 103(a) as being obvious over Ewart. *Response*, page 12. Specifically, Applicants allege that Pankratz does not remedy the alleged deficiencies of Ewart as directed to claim 1. *Id.* For the foregoing reasons, however, Ewart appropriately teaches the claimed invention. Moreover, Applicants have not traversed Ewart and Pankratz with respect to the specific limitations recited in claim 14.

IV. Conclusion

For the foregoing reasons and despite the claim amendment, the prior art rejections are maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2872. The examiner can normally be reached on Monday to Friday (8:30 am to 5:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon Y. Lum/
Examiner, Art Unit 1641

/Nelson Yang/
Primary Examiner, Art Unit 1641